



DEPARTMENT OF DEFENSE

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Office of the Secretary

32 CFR Part 199

DOD-2011-HA-0085

RIN – 0720-AB54

TRICARE; Removal of the Prohibition to Use Addictive Drugs in the Maintenance Treatment of Substance Dependence in TRICARE Beneficiaries

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Final rule.

SUMMARY: The Department of Defense (DoD) is publishing this final rule to remove the exclusion of drug maintenance programs and allow TRICARE coverage of the substitution of a therapeutic drug, with addictive potential, for a drug of addiction when medically necessary and appropriate as part of a comprehensive treatment plan for an individual with substance use dependence. The current regulation prohibits coverage of drug maintenance programs where one addictive substance is substituted for another. The final rule allows TRICARE to cover, as part of otherwise authorized treatment of substance use disorder, utilization of a specific category of psychoactive agent when medically necessary and appropriate. Removal of the exclusion is based on recognition of the accumulated medical evidence supporting the use of certain pharmacotherapies as one component in the continuum of opioid treatment services. Medication assisted treatment, to include drug maintenance involving substitution of a therapeutic drug with addiction potential, for a drug of addiction, is now generally accepted by qualified professionals to be reasonable and adequate as a component in the safe and effective treatment of substance

use disorders treatment services, and thus appropriate for inclusion as a component in the TRICARE authorized substance use disorder treatment for beneficiaries.

DATES: *Effective Date:* This rule is effective [insert date 30 days from date of publication in Federal Register]

FOR FURTHER INFORMATION CONTACT: John Davison, Ph.D., TRICARE Management Activity, Office of the Chief Medical Officer, telephone (703) 681-0086.

SUPPLEMENTARY INFORMATION:

I. Executive Summary.

A. Purpose of the Final Rule.

1. Need for the Regulatory Action

The original implementing regulations for the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), first issued in 1977, excluded drug maintenance programs from coverage. The DoD, consistent with chapter 55 of title 10, United States Code and other third party payors, covered medical services and supplies which were medically or psychologically necessary to prevent, diagnose, or treat a mental or physical illness, injury or bodily malfunction. At that time, drug maintenance programs were not the standard of care and were not generally accepted by qualified professionals to be medically necessary and appropriate for the diagnosis and treatment of an illness, injury, or mental disorder. The regulatory language has remained unchanged for over 35 years. This final rule changes TRICARE's coverage policy based on the acceptance of drug maintenance as an integral part of opioid treatment services, when medically necessary and as part of a comprehensive treatment plan for an individual with substance use disorder.

2. Legal Authority for the Regulatory Action

This regulation is proposed under the authorities of 10 U.S.C. section 1073, which authorizes the Secretary of Defense to administer the medical and dental benefits provided in chapter 55 of title 10, United States Code. The Department is authorized to provide medically necessary and appropriate medical care for mental and physical illnesses, injuries and bodily malfunctions, including hospitalization, outpatient care and drugs under 10 U.S.C. section 1077(a)(1)-(3). Although section 1077 defines benefits to be provided in the military treatment facilities (MTFs), these benefits are incorporated by reference for the benefits provided in the civilian health care sector to active duty family members and retirees and their dependents through section 1079 and 1086 respectively.

B. Summary of the Major Provisions of the Final Rule.

In this rule, the proposed regulatory language eliminates the specific regulatory exclusion of drug maintenance programs found at 32 CFR 199.4(e)(11)(ii). Further, this rule also revises both 32 CFR 199.4(e)(4)(ii) and (e)(11) to affirmatively include substitution of a therapeutic drug with addictive potential, for a drug of addiction as a component in an otherwise authorized substance use disorder treatment benefit, when medically necessary and appropriate medical care for a beneficiary undergoing medically supervised treatment for a substance use disorder.

C. Costs and Benefits.

This rule is not anticipated to have a significant impact on TRICARE costs. All services and supplies authorized under the TRICARE Basic Program must be determined to be medically necessary in the treatment of an illness, injury or bodily malfunction before the care can be cost shared by TRICARE. For this reason, DoD anticipates that TRICARE will have a marginal increase in cost associated with the inclusion of drug maintenance programs within the

TRICARE substance use disorder treatment benefit. The benefit of this rule is to improve substance use disorder treatment under TRICARE.

II. Discussion of the Final Rule.

The practice of medicine is constantly evolving, including in the area of substance use disorder treatment. At the implementation of the original CHAMPUS regulation, the Department of Defense, consistent with other third party payors, provided coverage based on what was generally accepted by qualified professionals to be reasonable and adequate in the treatment of substance use disorders. Based on current medical evidence, this exclusion of medication assisted treatment of substance use dependence utilizing a specific category of psychoactive agent is outdated and fails to recognize that the current standard of practice supports the medical necessity and appropriate medical care of certain drug maintenance programs as one component of the continuum of opioid treatment services that are medically or psychologically necessary for the effective treatment of substance dependence.

The Institute of Medicine (IOM) of the National Academies of Science completed a report in September 2012, entitled “Substance Use Disorders in the U.S. Armed Forces,” <http://www.iom.edu/Reports/2012/Substance-Use-Disorders-in-the-US-Armed-Forces.aspx>. The IOM found that the standards of care for substance use disorders are changing to reflect the inclusion of research-based pharmacological therapies. This final rule to permit the use of evidence-based pharmacological therapies is consistent with the recommendations of the IOM as well as the 2007 National Quality Forum’s National Voluntary Consensus Standards for the Treatment of Substance Use Conditions. TRICARE currently limits pharmaceutical therapy to acute detoxification but does not cover medications like buprenorphine and naloxone when used for either prolonged ambulatory detoxification (greater than 30 days) or maintenance therapy.

Evidence-based modalities of care in the treatment of substance use disorders include the use of agonist and antagonist medications that help to reduce cravings, maintain functioning and support long-term recovery. This type of pharmacological therapy has been described by a number of different terms including “drug maintenance programs,” “substitution therapy,” “medication assisted treatment,” “prolonged detoxification,” “prolonged withdrawal management,” “short-term maintenance,” “long term maintenance,” and “pharmacological therapy.”

Documented increases in the prescription of opioid pain medications throughout the United States have resulted in subsequent increases in opioid dependence and abuse in both the civilian and military populations. Service members are returning home from the wars in Iraq and Afghanistan with severe and painful injuries that require opioid pain management using medications that have the potential for addiction. The advances in battlefield injury protection and medicine have drastically reduced the number of battlefield deaths and have returned some of our Service members home, injured, but prepared to recover. For many, pain related to injuries must be treated for many months, and such long-term use of pain medications has put some of our Service members using those medicines at risk for opioid dependence. Many of the medical conditions that prevail in a heavily deployed force have also led to frequent prescriptions for controlled substances, which are high risk for addiction or misuse. Additionally, for our broader beneficiary population, the unintended consequence of compassionate pain management includes an escalation in the use of prescription opioid analgesics for medical purposes which can result in dependency and other adverse effects. This reality makes it ever more important to ensure that all medically or psychologically necessary and appropriate medical care for substance

use disorder are available to our TRICARE beneficiaries; consistent with the authority to provide treatment for mental or physical illness.

III. Public Comments.

The proposed rule was published in the Federal Register (76 FR 81899-80901) on December 29, 2011, for a 60 day public comment period. We received comments from 35 respondents. A large majority of commenters, 33 of 35 in total, expressed support for the rule change. Two comments opposed the rule change. We thank those who provided comments. Specific matters raised by commenters and the Department's responses are summarized below.

Comment: Two commenters who expressed strong support for the rule objected to use of the term “addictive drugs.” One respondent was concerned that the terminology conveys stigma. Another objected to categorizing substitution medications like buprenorphine as addictive drugs because once a patient is stabilized on these medications, the patient no longer meets DSM-IV criteria for substance dependence.

Response: We appreciate the comments and are mindful that terms conveying stigma create barriers to care. The exact language used in the proposed rule was derived from the existing regulatory language prohibiting coverage “when one addictive drug is substituted for another.” We have carefully considered terminology as a result of these comments and conclude it would be appropriate to replace “addictive drugs” in 32 CFR 199.4(e)(11) with “the substitution of a therapeutic drug with addictive potential for a drug of addiction” as a more neutral term that accurately describes substitution medications. To clarify the comment about DSM-IV diagnostic criteria for substance dependence, six treatment specifiers addressing the treatment recovery process are listed under the “Substance Dependence” section in the DSM-IV, including “On Agonist Therapy.” This specifier accurately describes the status of one whose

substance use disorder is in a state of remission while on the agent during a specific phase of treatment recovery.

Comment: Eight respondents who support the rule emphasized that substitution medications should only be used within the context of a comprehensive addiction treatment program.

Response: We agree that the substitution of a therapeutic drug with addiction potential for a drug of addiction, when medically or psychologically necessary and appropriate medical care, should not be used in isolation but rather utilized as one component of a comprehensive treatment plan for an individual with a substance use disorder. To clarify this point, we have added language in the amended provision at 32 CFR 199.4(e)(11) specifically limiting coverage to otherwise authorized substance use disorder treatment under 32 CFR 199.4(e)(4)(ii).

We also recognize that treatment must meet the specific patient's medical needs and is not necessarily amenable to a one-size-fits-all approach. Medication assisted treatment will not be medically necessary or appropriate in all cases. To clarify this, paragraph 32 CFR 199.4(e)(4)(ii) has been revised specifically to include, as a TRICARE covered service, the substitution of a therapeutic drug with addictive potential, for a drug addiction when medically or psychologically necessary and appropriate medical care for a beneficiary undergoing medically supervised treatment for a substance use disorder.

Several of the comments also made reference to approval for office-based practitioners as well. To the extent any of these comments were intended to seek to expand TRICARE authorized providers for substance use disorder inpatient and outpatient care, these comments fall outside the scope of the provisions of the proposed rule. We appreciate the comments and will take them into consideration in developing future rulemaking.

Comment: One commenter requests that TRICARE not impose treatment limits on the duration of opioid treatment.

Response: We concur that treatment limits should be guided by the patient's clinical condition and treatment needs. Studies have shown that good outcomes from substance abuse treatment are unequivocally contingent on adequate length of treatment. Although the current substance use disorder benefits contain treatment limitations, see specifically 32 CFR 199.4(e)(4)(ii), the existing regulation at 32 CFR 199.4(e)(4)(v) allows for waiver of limits based on individual treatment needs. This type of provision helps to ensure TRICARE beneficiaries have access to medically or psychologically necessary and appropriate medical care for substance use disorders. We appreciate this comment and will also take it into consideration in developing any future rulemaking regarding TRICARE substance use disorder treatment.

Comment: Two commenters request that TRICARE not impose high deductibles and co-payments on individual visits to decrease the likelihood that high costs become a barrier to care.

Response: We concur that access to care is important for beneficiaries seeking opioid addiction treatment. In general, TRICARE provides beneficiaries with a robust health care benefit with limited out-of-pocket costs. TRICARE deductibles and cost shares are set by Congress in statute. Beneficiaries are further protected by statutorily imposed catastrophic caps that limit the maximum out-of-pocket amounts beneficiaries will have to pay each fiscal year, with a few exceptions. The cap applies to annual deductibles, pharmacy copayments, TRICARE Prime enrollment fees and all other copayments or cost shares beneficiaries pay for TRICARE-covered services. Active duty family members and beneficiaries enrolled in TRICARE Reserve Select have a \$1,000 per family, per fiscal year catastrophic cap. The catastrophic cap for other beneficiaries is \$3,000 per family, per fiscal year.

Comment: One of two respondents who objected to the proposed rule change, indicated that opioid maintenance treatment on a long term basis has not been proven to improve function or reduce mortality or relapse in opioid addicted individuals and that research is based on short term studies. The respondent also expressed concern that the provision of medication assisted treatment is actually enabling substance abuse.

Response: We do not agree. Standards of care and best practices in the prevention, diagnosis, treatment, and management of substance use disorders have changed considerably over the course of the past decade to reflect developments in the evidence base. The use of evidence-based practices in substance use dependence care is integral to ensuring that individuals receive medically necessary and appropriate medical care that is effective, high-quality care. The September 2012, IOM report discusses in greater detail the evidence base, including randomized controlled trials, that support the use of pharmacotherapies in substance use dependence treatment.

Comment: The second objector asks why tax dollars should go to help those who made a decision to partake in illegal activity.

Response: By law, TRICARE beneficiaries are entitled to medically or psychologically necessary and appropriate medical care in the treatment of mental or physical illness unless otherwise excluded by law and regulation.

Regulatory Procedures.

Executive Order 12866, “Regulatory Planning and Review” and EO 13563, “Improving Regulation and Regulatory Review”

Section 801 of title 5, United States Code, and Executive Orders (EOs) 12866 and 13563 require certain regulatory assessments and procedures for any major rule or significant regulatory

action, defined as one that would result in an annual effect of \$100 million or more on the national economy or which would have other substantial impacts. It has been certified that this rule is not an economically significant rule, but it has been designated a significant regulatory action.

Public Law 104-4, Section 202, “Unfunded Mandates Reform Act”

Section 202 of Public Law 104-4, “Unfunded Mandates Reform Act,” requires that an analysis be performed to determine whether any federal mandate may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector of \$100 million in any one year. It has been certified that this rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year, and thus this rule is not subject to this requirement.

Public Law 96-354, “Regulatory Flexibility Act” (RFA) (5 U.S.C. 601)

Public Law 96-354, “Regulatory Flexibility Act” (RFA) (5 U.S.C. 601), requires that each Federal agency prepare a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This rule is not an economically significant regulatory action, and it has been certified that it will not have a significant impact on a substantial number of small entities. Therefore, this rule is not subject to the requirements of the RFA.

Public Law 96-511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)

This rule does not contain a “collection of information” requirement, and will not impose additional information collection requirements on the public under Public Law 96-511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35).

Executive Order 13132, “Federalism”

E.O. 13132, “Federalism,” requires that an impact analysis be performed to determine whether the rule has federalism implications that would have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. It has been certified that this rule does not have federalism implications, as set forth in E.O. 13132.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR Part 199 is amended as follows:

PART 199 – [AMENDED]

1. The authority citation for Part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.4 is amended by revising paragraphs (e)(4)(ii) introductory text and (e)(11) introductory text, and removing and reserving paragraph (e)(11)(ii), to read as follows:

§ 199.4 Basic program benefits.

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(e) * * *

(4) * * *

(ii) *Authorized substance use disorder treatment.* Only those services provided by TRICARE-authorized institutional providers are covered. Such a provider must be either an authorized hospital, or an organized substance use disorder treatment program in an authorized free-standing or hospital-based substance use disorder rehabilitation facility. Covered services

consist of any or all of the services listed below, including the substitution of a therapeutic drug, with addictive potential, for a drug addiction when medically or psychologically necessary and appropriate medical care for a beneficiary undergoing medically supervised treatment for a substance use disorder. A qualified mental health provider (physicians, clinical psychologists, clinical social workers, psychiatric nurse specialists) (see paragraph (c)(3)(ix) of this section) shall prescribe the particular level of treatment. Each TRICARE beneficiary is entitled to three substance use disorder treatment benefit periods in his or her lifetime, unless this limit is waived pursuant to paragraph (e)(4)(v) of this section. (A benefit period begins with the first date of covered treatment and ends 365 days later, regardless of the total services actually used within the benefit period. Unused benefits cannot be carried over to subsequent benefit periods. Emergency and inpatient hospital services (as described in paragraph (e)(4)(i) of this section) do not constitute substance abuse treatment for purposes of establishing the beginning of a benefit period.)

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(11) *Drug abuse.* Under the Basic Program, benefits may be extended for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care (refer to paragraph (d) of this section). However, TRICARE benefits cannot be authorized to support or maintain an existing or potential drug abuse situation whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means. Drugs, including the substitution of a therapeutic drug with addictive potential for a drug of addiction, prescribed to beneficiaries undergoing medically supervised treatment for a substance use disorder as authorized under paragraph (e)(4)(ii) of this section are not considered to be in support of, or to maintain, an existing or potential drug abuse situation

and are allowed. The Director, TRICARE Management Activity, may prescribe appropriate policies to implement this prescription drug benefit for those undergoing medically supervised treatment for a substance use disorder.

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(ii) [Reserved]

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DATED: September 26, 2013.

Patricia L. Toppings
OSD Federal Register Liaison Officer
Department of Defense

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